PROGRAM ANNOUNCEMENT (PA) TITLE: INCREASING QUALITY OF LIFE IN MOBILITY DISORDERS

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PARTICIPATING INSTITUTES AND CENTERS (ICs):
National Institute of Nursing Research (NINR)
(www.nih.gov/ninr)
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
(www.niams.nih.gov)
National Institute of Child Health and Human Development (NICHD)
(www.nichd.nih.gov)
National Institute of Neurological Disorders and Stroke (NINDS)
(www.ninds.nih.gov)

THIS PA CONTAINS THE FOLLOWING INFORMATION

PURPOSE OF THIS PA

The National Institute of Nursing Research (NINR), the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the National Institute of Child Health and Human

Development (NICHD), and the National Institute of Neurological Disorders and Stroke (NINDS) seek research grant applications that will improve the quality of life for people living with mobility limiting disorders. Persons with limited mobility may also experience secondary conditions that further limit mobility. These secondary symptoms or sequelae include pain, fatigue, spasticity, weakness and depression. This Program Announcement will focus on improving the quality of life in persons with limited mobility by managing the physical symptoms and psychosocial consequences that occur as a result of the primary or secondary condition.

RESEARCH OBJECTIVES

There has been limited research on the psychosocial effects and the quality of life experienced by persons with conditions that limit mobility. Conditions that limit mobility include degenerative conditions such as multiple sclerosis, Parkinson's disease; injuries such as stroke, and traumatic brain or spine injuries; and congenital abnormalities such as cerebral palsy. Other examples of conditions that may limit mobility are obesity, arthritis, lower limb ischemia, pulmonary disorders and balance disorders.

In addition to limited mobility, symptoms of pain and fatigue are common and may have a synergistic negative effect on psychosocial and physical functioning. Severe uncontrolled spasticity as found in multiple sclerosis, amyotrophic lateral sclerosis, spinal cord injury and cerebral palsy may cause further pain and affect the individual's physical functioning and quality of life. Interventions are needed to reduce spasticity and maintain functioning of muscles. Other persons may have chronic pain that can disrupt sleep, which has a further impact upon the fatigue that patients may be experiencing. In addition, limited mobility, pain, fatigue and sleep disruption may be associated with depression. Interventions are needed to address this symptom complex.

Strategies to improve coping with symptoms in conditions with limited mobility will improve quality of life for these individuals. However, there may be a varying progression of the symptoms found in primary mobility disorders that may require additional strategies to cope both physically and psychologically with the disease. Examples of a varying course include the abrupt onset of symptoms, a waxing and waning of symptoms, a progressive slow decline in symptoms or stability of symptoms throughout the course of the disease. For example, stroke patients may experience an abrupt loss in their ability to move and perform activities of daily living. This abrupt change in ability to perform activities of daily living suggests the need for interventions to promote additional coping strategies that are not necessary in a mobility condition that has been stable for many years.

Other chronic conditions may exhibit steady progression or may have a waxing and waning course. These include multiple sclerosis, amyotrophic lateral sclerosis, and Parkinson's disease. The ability to adjust and cope with the course of these diseases may require different coping strategies in comparison to conditions in which there is no progressive decline. The unpredictability of the course of the disease may require additional coping strategies to maintain positive psychosocial and physical functioning. Active problem focused coping has been found to be associated with a better psychosocial adjustment in a variety of conditions. Research determining whether there are unique strategies to cope with varying courses of disease or stages of disease or if there are certain strategies that work best across all diseases is needed.

Maintaining of/or improving functional ability and preventing secondary symptoms or sequelae is hypothesized to improve quality of life in persons with limited mobility. Quality of life is closely associated with independent living, but independence is not always possible with some mobility limiting disorders. Thus, there may be a need for caregivers to help accomplish activities of daily living. The anticipation of becoming dependent and being dependent upon others may be an additional stressor for individuals.

Other psychosocial consequences are the decreased employment and financial status that may accompany conditions with limited mobility. In addition, limited mobility may increase feelings of anxiety, depression, and social isolation, and decrease feelings of self-esteem. Depression and anxiety are often under diagnosed in individuals with conditions with limited mobility and are significant contributors to decreased quality of life. In general, depression and anxiety demonstrate a weak association with the severity of the limitation of mobility. Identification of the factors or individual differences associated with mood disturbances that can influence quality of life is needed in persons with limited mobility.

Quality of life in individuals with limited mobility needs to be improved across the lifespan and across different ethnic/cultural groups. Little research has been conducted to determine whether there are gender and cultural/ethnic influences in response to diagnosis and adherence to treatment regimens in conditions of limited mobility.

Research to improve functional ability in children with limited mobility has been conducted. However, in certain conditions such as severe cerebral palsy and cystic fibrosis, the survival rate is now longer due to medical advances. Little is known about the psychosocial and medical needs of these adults and how their shift from a focus on premature death to living with some chronic functional limitation such as immobility influences quality of life.

As individuals age, there is an association with increasing immobility. The weakness, stiffness and pain associated with the impairment of musculoskeletal functioning results in decreased mobility and potentially a decreased quality of life. Interventions to maintain strength and endurance in physical functioning may delay some of the disabilities associated with aging as well as improve psychosocial functioning. Studies are needed on approaches to preventing, maintaining and restoring functional ability in elderly and other populations with limited mobility.

Listed below are examples of studies that would be responsive to this program announcement. However, these are only illustrative examples and applicants are encouraged to propose other topics consistent with the goals of this program.

o Identify innovative interventions to improve and/or maintain physical functioning in conditions with limited mobility across the lifespan
o Identify unique interventions to maintain physical functioning in challenging populations such as the cognitively impaired elderly with limited mobility
o Identify strategies to improve quality of life and psychosocial adjustment in individuals with limited mobility
o Identify unique coping strategies to manage the varying course of symptoms found in waxing and waning conditions, a steadily progressive decline, or an abrupt onset, versus a stable condition
o Develop strategies to minimize the secondary symptoms of pain and fatigue that may be found in persons with limited mobility
o Explore whether gender and racial/ethnic influences occur in response to the physical and psychosocial functioning in persons with limited mobility
o Develop and test interventions to address the fear of functional dependence and reduce the need for relying upon others for accomplishing the activities of daily living
o Determine the factors contributing to quality of life and positive outcomes for individuals experiencing a mobility disorder
o Determine factors associated with successful adaptation to a sudden decrease in mobility
o Identify barriers to maximal physical and psychosocial functioning in persons with limited mobility
o Identify unique factors that promote quality of life in people who have mobility limitation secondary to conditions such as pulmonary disease and obesity
o Identify innovative interventions to improve/and or maintain physical functioning in conditions with limited mobility in children, adolescents and young adults making their transition to the workforce

o Determine the factors contributing to quality of life and positive outcomes for individuals with mental retardation experiencing a mobility disorder
o Identify physical or psychosocial factors and coping strategies associated with use of assistive devices or neural prostheses and their effectiveness in helping patients to overcome limited mobility
o Evaluate the impact on psychosocial functioning or quality of life of the use of assistive devices or neural prostheses in managing mobility limitation.

For all proposed research, appropriate methods should be applied for the quantitative assessment of the psychosocial and quality of life components in research on mobility limitation and intervention strategies for this population.

MECHANISMS OF SUPPORT

This PA will use the NIH R01 and R21 award mechanisms. As an applicant, you will be solely responsible for planning, directing, and executing the proposed project. The objective of the exploratory/developmental mechanism (R21) is to encourage applications from individuals who are interested in testing innovative or conceptually creative ideas that are scientifically sound and may advance our understanding of quality of life in mobility disorders. Investigators are encouraged to explore the feasibility of an innovative research question or approach that will provide a basis for future research project applications. Exploratory/developmental grants (R21) are limited to 2 years of support and up to $150,000 per year in direct costs.

This PA uses just-in-time concepts. It also uses the modular as well as the non-modular budgeting formats (see http://grants.nih.gov/grants/funding/modular/modular.htm). Specifically, if you are submitting an application with direct costs in each year of $250,000 or less, use the modular format. Otherwise follow the instructions for non-modular research grant applications.

ELIGIBLE INSTITUTIONS

You may submit (an) application(s) if your institution has any of the following characteristics:

o For-profit or non-profit organizations
o Public or private institutions, such as universities, colleges, hospitals, and laboratories
o Units of State and local governments
o Eligible agencies of the Federal government

o Domestic or foreign
o Faith Based Organizations

INDIVIDUALS ELIGIBLE TO BECOME PRINCIPAL INVESTIGATORS

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs.

WHERE TO SEND INQUIRIES

We encourage your inquiries concerning this PA and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into two areas: scientific/research and financial or grants management issues:

o Direct your questions about scientific/research issues to:

Dr. Karin Helmers
Office of Extramural Programs
National Institute of Nursing Research
Building 45, Room 3AN12
Bethesda, MD 20892-6300
Telephone: (301) 594-2177
FAX: (301) 480-8260
Email: karin.helmers@nih.gov

Dr. Deborah N. Ader
Director, Behavioral and Prevention Research Program
NIAMS
45 Center Dr., Building 45
Rm 5As19H
Bethesda, MD 20892
Tel: (301) 594-5032
Fax: (301) 480-4543

Dr. Louis Quatrano

Behavioral Sciences and Rehabilitation Engineering
National Institute of Child Health and Human Development
6100 Executive Boulevard, 2A03, MSC 7510
Bethesda, MD 20892-7510
Telephone: (301) 402-4221
FAX: (301) 496-0832
Email: quatranl@exchange.nih.gov

Dr. Daofen Chen
Channels, Synapses, and Circuits
National Institute of Neurological Disorders and Stroke
6001 Executive Boulevard, Room 2131
Bethesda, MD 20892-9523
Telephone: 301-496-1917
FAX: 301-402-1501
Email: daofen_chen@nih.gov

o Direct your questions about financial or grants management matters to:

Ms. Cynthia McDermott
Office of Grants and Contracts Management
National Institute of Nursing Research
Building 45, Room 3AN12
Bethesda, MD 20892-6300
Telephone: (301) 594-6869
FAX: (301) 480-8260
Email: cindy.mcdermott@nih.gov

Ms. Melinda Nelson
Chief Grants Management Officer
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Natcher Building Room 5AS.49F - MSC 6500
Bethesda, MD 20892-6500
Telephone: (301) 594-3535
FAX: (301) 480-5450
Email: nelsonm@exchange.nih.gov

Mr. Christopher Myers
Grants Management Branch
National Institute of Child Health and Human Development
6100 Executive Boulevard, 8A17, MSC 7510
Telephone: 301-435-6996
FAX: 301-402-0915
Email: cm143g@nih.gov

Ms. Aricia Cottman
Grants Management Branch
National Institute of Neurological Disorders and Stroke
6001 Executive Boulevard, Room 3290
Bethesda, MD 20892
Telephone: 301-496-9231
Fax: 301-402-0219
Email: cottmana@ninds.nih.gov

SUBMITTING AN APPLICATION

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001). The PHS 398 is available at http://grants.nih.gov/grants/funding/phs398/phs398.html in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

APPLICATION RECEIPT DATES: Applications submitted in response to this program announcement will be accepted at the standard application deadlines, which are available at http://grants.nih.gov/grants/dates.htm. Application deadlines are also indicated in the PHS 398 application kit.

SPECIFIC INSTRUCTIONS FOR MODULAR GRANT APPLICATIONS: Applications requesting up to $250,000 per year in direct costs must be submitted in a modular grant format. The modular grant format simplifies the preparation of the budget in these applications by limiting the level of budgetary detail. Applicants request direct costs in $25,000 modules. Section C of the research grant application instructions for the PHS 398 (rev. 5/2001) at http://grants.nih.gov/grants/funding/phs398/phs398.html includes step-by-step guidance for preparing modular grants. Additional information on modular grants is available at http://grants.nih.gov/grants/funding/modular/modular.htm.

SPECIFIC INSTRUCTIONS FOR APPLICATIONS REQUESTING $500,000 OR MORE PER YEAR:
Applications requesting $500,000 or more in direct costs for any year must include a cover letter identifying the NIH staff member within one of NIH institutes or centers who has agreed to accept assignment of the application.

Applicants requesting more than $500,000 must carry out the following steps:

Contact the IC program staff at least 6 weeks before submitting the application, i.e., as you are developing plans for the study;

2) Obtain agreement from the IC staff that the IC will accept your application for consideration for award; and,

3) Identify, in a cover letter sent with the application, the staff member and IC who agreed to accept assignment of the application.

This policy applies to all investigator-initiated new (type 1), competing continuation (type 2), competing supplement, or any amended or revised version of these grant application types. Additional information on this policy is available in the NIH Guide for Grants and Contracts, October 19, 2001 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html.

SENDING AN APPLICATION TO THE NIH: Submit a signed, typewritten original of the application, including the checklist, and five signed photocopies in one package to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710
Bethesda, MD 20817 (for express/courier service)

APPLICATION PROCESSING: Applications must be received by or mailed on or before the receipt dates described at http://grants.nih.gov/grants/funding/submissionschedule.htm. The CSR will not accept any application in response to this PA that is essentially the same as one currently pending initial review unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already reviewed. This does

not preclude the submission of a substantial revision of an application already reviewed, but such application must include an Introduction addressing the previous critique.

PEER REVIEW PROCESS

Applications submitted for this PA will be assigned on the basis of established PHS referral guidelines. An appropriate scientific review group convened in accordance with the standard NIH peer review procedures (http://www.csr.nih.gov/refrev.htm) will evaluate applications for scientific and technical merit.

As part of the initial merit review, all applications will:

o Receive a written critique
o Undergo a selection process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed and assigned a priority score
o Receive a second level review by the appropriate national advisory council or board

REVIEW CRITERIA

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written comments, reviewers will be asked to discuss the following aspects of your application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals:

o Significance
o Approach
o Innovation
o Investigator
o Environment

The scientific review group will address and consider each of these criteria in assigning your application's overall score, weighting them as appropriate for each application. Your application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, you may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

(1) SIGNIFICANCE: Does your study address an important problem? If the aims of your application are achieved, how do they advance scientific knowledge? What will be the effect of these studies on the concepts or methods that drive this field?

(2) APPROACH: Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Do you acknowledge potential problem areas and consider alternative tactics?

(3) INNOVATION: Does your project employ novel concepts, approaches or methods? Are the aims original and innovative? Does your project challenge existing paradigms or develop new methodologies or technologies?

(4) INVESTIGATOR: Are you appropriately trained and well suited to carry out this work? Is the work proposed appropriate to your experience level as the principal investigator and to that of other researchers (if any)?

(5) ENVIRONMENT: Does the scientific environment in which your work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

ADDITIONAL REVIEW CRITERIA: In addition to the above criteria, your application will also be reviewed with respect to the following:

PROTECTIONS: The adequacy of the proposed protection for humans, animals, or the environment, to the extent they may be adversely affected by the project proposed in the application.

INCLUSION: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated. (See Inclusion Criteria included in the section on Federal Citations, below)

DATA SHARING: The adequacy of the proposed plan to share data.

BUDGET: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research.

AWARD CRITERIA

Applications submitted in response to a PA will compete for available funds with all other recommended applications. The following will be considered in making funding decisions:

o Scientific merit of the proposed project as determined by peer review
o Availability of funds
o Relevance to program priorities

REQUIRED FEDERAL CITATIONS

MONITORING PLAN AND DATA SAFETY AND MONITORING BOARD: Research components involving Phase I and II clinical trials must include provisions for assessment of patient eligibility and status, rigorous data management, quality assurance, and auditing procedures. In addition, it is NIH policy that all clinical trials require data and safety monitoring, with the method and degree of monitoring being commensurate with the risks (NIH Policy for Data Safety and Monitoring, NIH Guide for Grants and Contracts, June 12, 1998: http://grants.nih.gov/grants/guide/notice-files/not98-084.html).

INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH: It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing clinical research should read the AMENDMENT "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html); a complete copy of the updated Guidelines are available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm.
The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy

continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS:
The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects that is available at http://grants.nih.gov/grants/funding/children/children.htm.

REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS: NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. You will find this policy announcement in the NIH Guide for Grants and Contracts Announcement, dated June 5, 2000, at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

HUMAN EMBRYONIC STEM CELLS (hESC): Criteria for federal funding of research on hESCs can be found at http://grants.nih.gov/grants/stem_cells.htm and at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (see http://escr.nih.gov). It is the responsibility of the applicant to provide the official NIH identifier(s)for the hESC line(s)to be used in the proposed research. Applications that do not provide this information will be returned without review.

PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT: The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is

important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm.

Applicants may wish to place data collected under this PA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

URLs IN NIH GRANT APPLICATIONS OR APPENDICES: All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

HEALTHY PEOPLE 2010: The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This PA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.health.gov/healthypeople.

AUTHORITY AND REGULATIONS: This program is described in the Catalog of Federal Domestic Assistance Nos. 93.361 (NINR), 93.846 (NIAMS), 93.929 (NICHD), 93.853 (NINDS) and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and administered under NIH grants policies described at http://grants.nih.gov/grants/policy/policy.htm and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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